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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/308,027	08/16/99	SONE T	06501/031001

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EXAMINER	
HUYNH,P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/308,027	SONE ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). Applicant's compliance with sequence's rule is acknowledged.

3. Applicant's preliminary amendment, filed on 12/11/00 (Paper No. 9), is acknowledged. Claims 1-15 are pending in instant application.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this Action, to elect a single invention to which the claims must be restricted:

I. Claims 1-3 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB5* 0101 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 3.

II. Claims 1-3 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB5* 0101 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 4.

III. Claims 1-3 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB5* 0101 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 14.

IV. Claims 1-3 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB5* 0101 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 19.

V. Claims 1-3 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB5* 0101 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 18.

VI. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 1.

VII. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 5.

VIII. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 7.

IX. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 9.

X. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 10.

XI. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 21.

XII. Claims 1-2, 5 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DQA1* 0102-DQB1*0602 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 23.

XIII. Claims 1-2, 6 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DPA1* 0102-DPB1*0501 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 2.

XIV. Claims 1-2, 6 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DPA1* 0102-DPB1*0501 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 8.

XV. Claims 1-2, 6 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DPA1* 0102-DPB1*0501 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 15.

XVI. Claims 1-2, 7 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DPA1* 0202-DPB1*0501 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 16.

XVII. Claims 1-2, 8 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DPA1* 0101-DPB1*0201 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 17.

XVIII. Claims 1-2, 9 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 0901 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 6.

XIX. Claims 1-2, 9 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 0901 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 12.

XX. Claims 1-2, 9 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 0901 wherein immunotherapeutic agent is Cry j 1 consisting of SEQ ID NO: 7.

XXI. Claims 1-2, 9 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 0901 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 16.

XXII. Claims 1-2, 9 and 11-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 0901 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 20.

XXIII. Claims 1-2 and 10-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 1501 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 13.

XXIV. Claims 1-2 and 10-15, drawn to a peptide based immunotherapeutic agent for treating an allergy patient having HLA class II, DRB1* 1501 wherein immunotherapeutic agent is Cry j 2 consisting of SEQ ID NO: 19.

The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The Invention of Group I was to have no special technical feature that defined the contribution over the prior art of Rogers *et al*, (Molecular Immunology 31(13): 955-966, 1994, IDS 1449), Hashiguchi *et al*. (Nippon Rinsho 54(8): 2233-42, Aug 1996) and Hori *et al*, (Tissue Antigens 47(6): 485-91, June 1996).

Rogers *et al* teaches peptide-based immunotherapy for allergy using peptide containing human T cell epitope specific for a particular allergen, including birch pollen allergen (See entire document).

Rogers *et al* differs from the instant inventions by not disclosing Japanese cedar major pollen allergens Cry j 1 and Cry j 2 and T cell specific epitope for said pollen allergens.

Hashiguchi *et al* teaches the use of T cell specific epitope of Japanese major cedar pollens Cry j 1 and Cry j 2 to modulate T cell response in peptide-based immunotherapy (See entire document).

Hori *et al* identifies the Cry j 1 immunodominant peptide of the Japanese cedar which induced MHC class II restricted Th2, including HLA-DP5 (DPA1*02022/DPB1*0501) which may involved in Japanese cedar pollinosis.

In re Kerkhoven, 205USPQ 1069 (CCPA 1980), recognized that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ... [T]he idea of combining them flows logically from their having being individually taught in the prior art" (see MPEP 2144.06).

It would have been obvious to combine the teaching of the references at the time the invention was made for the same purpose because conventional immunotherapy using allergen extract (whole peptide) has shown to be effective in desensitized patients with cedar pollen allergy. Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
February 28, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
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